REMARKS

Applicants have filed a Request For Continued Examination herewith.

The above-referenced application has been amended to indicate that this application is a continuation-in-part of prior application Serial Number 09/328,764, filed June 9, 1999. The prior application has issued as US Patent No. 6,214,815.

Claims 1-17 were pending in this application at the time the Final Office Action was issued. Claims 1-17 have been cancelled. New claims 18-22 have been added.

Applicants believe that with the cancellation of original claims 1-17 and the addition of new claims 18-22 the rejection issued by the Examiner under 35 U.S.C. § 112, first paragraph, has been traversed. New claims 18 and 21 recite a specific estrogen, ethinyl estradiol, and a specific progestin, desogestrel. Moreover, these claims recite a specific dosage of ethinyl estradiol and desogestrel administered in each phase of the triphasic regimen encompassed by the claims. Accordingly, the objection raised by the Examiner with respect to undue experimentation is moot. Claims 18-22 are fully supported by the specification. Note, for example, page 7, line 11 to page 8, line 2, and, page 21, Example 2.

The rejection issued by the Examiner under 35 U.S.C. § 112, second paragraph, has also been traversed, since new claims 18-22 do not include the terms "progestogen equivalent" or "estrogen equivalent".

Claims 1-17 were rejected under 35 U.S.C. § 103 as being unpatentable over Pasquale '839 and Darney. Applicants request that this rejection be withdrawn in view of the cancellation of claims 1-17 and the addition of new claims 18-22.

Claims 18-22 define a low-dose estrogen, triphasic desogestrel regimen that is neither taught nor suggested by either Pasquale or Darney. The Examiner admits that, even with respect to original claims 1-17, the cited art does not disclose the specific administration levels of the claimed medicaments. This shortcoming of the prior art is even more pronounced with respect to new claims 18-22, since nether Pasquale nor Darney teach or even suggest the particular contraceptive hormones and the specific administration levels of these hormones recited in the new claims.

The Examiner argues that Darney teaches altering and/or increasing the progestin dosage to alleviate irregular bleeding in women taking combined oral contraceptive regimens. In particular, the Examiner cites page 2, column 2, paragraph 2; and page 3, column 2,

paragraph 1 of Darney. The Examiner maintains that these teachings provide motivation to modify the cited art into the present invention.

Applicants point out, however, that the portions of Darney relied on by the Examiner teach directly away from the claimed invention. Darney specifically states that for women experiencing bleeding problems switching to a pill with higher estrogen content, 30-35 μg or even a 50 μg product, may be indicated. Darney goes even further when he recommends supplementing regular OC use with additional conjugated estrogen or estrone sulfate. This is in direct opposition to the present invention wherein the claims define a low-dose oral contraceptive regimen that provides good bleeding control at an ethinyl estradiol daily dosage of only 25μg.

Accordingly, a fair reading of the cited references fails to provide the motivation for modifying the prior art into the claimed invention argued for by the Examiner. Instead, the cited art would lead a person skilled in the art directly away from the lose-dose regimen defined in claims 18-22 to a regimen requiring a high daily dose of estrogen.

In view of the foregoing, applicants believe that new claims 18-22 patentably distinguish over the cited art and applicants request that a Notice of Allowance directed to these claims be issued at the earliest possible date.

Applicants hereby petition for a three-month extension of time in order to respond to the Final Action dated July 30, 2003. Please charge the fee of $930.00 required under 37 C.F.R. § 1.17(a)(3), any deficiency in this fee and any other fees that may be required to Deposit Account No. 10-0750/ORT-1373/JSK.

Should the Examiner have any questions regarding this Amendment, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

By: _____
Joseph S. Kentoffio
Reg. No. 33,189

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3711
Dated: January 29, 2003
Customer No. 000027777

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Page 1

After the Title but before the first paragraph, please insert the following paragraph:

Cross-reference to Related Application

-- This application is a continuation in part of prior application Serial Number 09/328,764, filed June 9, 1999, now US Patent No. 6, 214,815, which is hereby incorporated by reference. --

In the Claims:

Please insert the following new claims:

18. (New) A method of contraception which comprises administering for 21 successive days to a female of child bearing age a combination of ethinyl estradiol and desogestrel in a contraceptively effective daily dosage in which there is a first phase of 5-8 days wherein the combination comprises an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.100 mg; followed by a second phase of 7-11 days wherein the combination comprises an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.125 mg; followed by a third phase of 3-7 days wherein the combination comprises an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.150 mg; and followed by 4-8 days free of estrogen and desogestrel administration.

19. (New) The method of claim 18, wherein the ethinyl estradiol and the desogestrel are administered orally and the period of each phase is seven days.

20. (New) The method of claim 1, wherein the ethinyl estradiol and the desogestrel are administered in admixture.

21. (New) A triphasic oral contraceptive unit having 21 separate dosage units adapted for successive daily oral administration comprising: 5-8 dosage units containing, in admixture with a pharmaceutically acceptable carrier, a combination of an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.100 mg as a first phase; followed by 7-11 dosage

units containing, in admixture with a pharmaceutically acceptable carrier, a combination of an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.125 mg as a second phase; followed by 3-7 dosage units containing, in admixture with a pharmaceutically acceptable carrier, an ethinyl estradiol daily dosage of 25 μg and a desogestrel daily dosage of 0.150 mg as a third phase; and optionally containing 4-8 additional dosage units free of ethinyl estradiol and desogestrel.

22. (New) The contraceptive unit according to claim 10, wherein the dosage units are in the form of tablets.

Please cancel claims 1-17:

[

1. A method of contraception which comprises administering for 21 successive days to a female of childbearing age a combination of an estrogen and a progestogen in a contraceptively effective daily dosage in which there is a first phase of 5-8 days where the combination comprises a progestogen equivalent in effect to about 0.065-0.75 mg of norethindrone and an estrogen equivalent in effect to about 23-28 μg of ethinyl estradiol; followed by a second phase of 7-11 days, where the combination comprises a progestogen equivalent in effect to about 0.25-1.0 mg of a norethindrone and an estrogen equivalent in effect to about 23-28 μg of ethinyl estradiol; followed by a third phase of 3-7 days where the combination comprises a progestogen equivalent in effect to about 0.35-2.0 mg of norethindrone in combination with an estrogen equivalent in effect to about 23-28 μg of ethinyl estradiol; and followed by 4-8 days which are free of hormone administration; with the provisos that the progestin dose should increase from the first phase to the second phase to the third phase, that the progestin is desogestrel at a dose in each phase of between of from 0.05-1.0 mg/day and that the dosage of estrogen is kept constant in each phase.

2. The method of claim 1 wherein the estrogen and progestogen are administered orally and the period specificed in each phase is seven days.

3. The method of claim 2 wherein the estrogen and progestogen are administered in admixture.

4. The method of claim 1 wherein the estrogen is selected from the group consisting of 17α-ethinylestradiol, mestranol, estrone, estrone sulfate piperazine salt, estradiol and estriol.

5. The method of claim 1 wherein the estrogen is selected from the group consisting of is 17α-ethinylestradiol or 17α-ethinylestradiol 3-methyl ether.

6. The method of claim 3 wherein the estrogen is 17α-ethinylestradiol.

7. The method of claim 3 wherein the estrogen is 17α-ethinylestradiol 3-methyl ether.

8. The method of claim 1 wherein the desogestrel daily dosage is 0.100 mg in the first phase, 0.125 mg in the second phase and 0.150 mg in the third phase and the estrogen daily dosage is 25 μg for each phase.

9. The method of claim 1 which comprises administering for 21 successive days to a female of childbearing age a combination of 17α-ethinylestradiol and desogestrel for the first 7 days in a daily dosage equal to 25 μg of 17α-ethinylestradiol and 0.100 mg of desogestrel, for the succeeding 7 days a daily dosage equal to 25 μg of 17α-ethinylestradiol and 0.125 mg of desogestrel; and for the next 7 days a daily dosage equal to 25 μg of 17α-ethinylestradiol and 0.150 mg of desogestrel; followed by 7 days without estrogen and progestogen administration.

10. A triphasic oral contraceptive unit having 21 separate dosage units, adapted for successive daily oral administration comprising: 5-8 dosage units containing, in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen and a progestogen at contraceptively effective dosages corresponding in estrogenic activity to 23-28 μg of 17α-ethinylestradiol and in progestogenic activity to 0.065-0.75 mg of norethindrone as a first

phase; followed by 7-11 dosage units containing in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen and a progestagen at a contraceptively effective dosage corresponding in estrogenic activity to 23-28 μg of 17α-ethinylestradiol and in progestogenic activity to 0.25-1.0 mg of norethindrone as a second phase; followed by 3-7 dosage units containing a admixture with a pharmaceutically acceptable carrier, a combination of an estrogen at a contraceptively effective dosage corresponding in estorgenic activity to 23-28 μg of 17α-ethinylestradiol and in progestogenic activity to 0.35-2.0 mg of norethindrone as a third phase; and optionally containing 4-8 additional dosage units free of estrogen and progestogen; with the provisos that the progestin dose should increase from the first phase to the second phase to the third phase, that the progestin is desogestrel at a dose in each phase of between of from 0.05-1.0 mg/day and that the dosage of estrogen is kept constant in each phase.

11. The contraceptive unit according to claim 10 wherein the dosage units are in the form of tablets.

12. The contraceptive unit according to claim 10 wherein the estrogen is selected from the group consisting of 17α-ethinylestradiol, mestranol, estrone, estrone sulfate, estrone sulfate piperazine salt, estradiol and estriol.

13. The contraceptive unit according to claim 10 wherein the estrogen is 17α-ethinylestradiol.

14. The contraceptive unit according to claim 10 wherein the estrogen is 17α-ethinylestradiol.

15. The contraceptive unit according to claim 10 wherein the estrogen is 17α-ethinylestradiol 3-methyl ether.

16. The contraceptive unit according to claim 10 wherein the estrogen daily dosage in all three phases is 25 μg of 17α-ethinylestradiol; and the desogestrel daily dosage is 0.100 mg of desogestrel in the first phase, 0.125 mg of desogestrel in the second phase and 0.150 mg of desogestrel in the third phase.

17. A triphasic oral contraceptive unit having 21 separate dosage units, adapted for successive daily oral administration comprising: 7 dosage units containing, in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen and a progestogen at contraceptively effective dosages corresponding in estrogenic activity to 23-28 μg of 17α-ethinylestradiol and in progestogenic activity to 0.065-0.75 mg of norethindrone as a first phase; followed by 7 dosage units containing in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen and a progestagen at a contraceptively effective dosage corresponding in estrogenic activity to 23-28 μg of 17α-ethinylestradiol and in progestogenic activity to 0.25-1.0 mg of norethindrone as a second phase; followed by 7 dosage units containing in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen at a contraceptively effective dosage corresponding in estrogenic activity to 23-28 μg of 17α-ethinylestradiol and in progestogenic activity to 0.35-2.0 mg of

norethindrone as a third phase; and optionally containing 7 additional dosage units free of estrogen and progestogen; with the provisos that the progestin dose should increase from the first phase to the second phase to the third phase, that the progestin is desogestrel at a dose in each phase of between of from 0.05-1.0 mg/day and that the dosage of estrogen is kept constant in each phase.]